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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/688,709	10/17/2003	Robert H. Harris	13095A	2201

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EXAMINER	
LUKTON, DAVID	
ART UNIT	**PAPER NUMBER**
1653	

DATE MAILED: 04/13/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/688,709	HARRIS, ROBERT H.	
	Examiner	Art Unit	
	David Lukton	1653	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 March 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *20-34,52,56 and 63-67* is/are pending in the application.

4a) Of the above claim(s) *29-31* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *20-28,32-34,52,56 and 63-67* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

Applicants' specie election is acknowledged, i.e., the following compound:

$$Ac\text{-}NH\text{-}CH(CH_2OMe)\text{-}CO\text{-}NH\text{-}CH_2\text{-}C_6H_5$$

Applicants have argued that if the "election of species" becomes a restriction requirement, it will be traversed. In response, no claim will be withdrawn that encompasses the elected specie. It is true that claims 29-31 are now withdrawn from consideration, since they do not encompass the elected specie. However, if claim 20 is found allowable in its present form, claims 29-31 will be rejoined therewith; if claim 20 found allowable in amended form, and if that amended form encompasses the subject matter of claims 29-31, these latter claims (29-31) will be rejoined with the elected claims.

Claims 20-34, 52, 56, 63-67 remain pending; claims 20-28, 32-34, 52, 56, 63-67 are examined in this Office action.

. . . .

The following abbreviations are used hereinbelow:

"**EWG**" represents an electron-withdrawing group

"**EDG**" represents an electron-donating group

"**EWG/EDG**" signifies that a group may be either electron-donating, or electron- withdrawing

✦

35 U.S.C. §101 reads as follows:

> "Whoever invents or discovers any new and useful process, machine, manufacture or composition of matter or any new and useful improvement therof, may obtain a patent therefore, subject to the conditions and requirements of this title".

Claims 20-28, 32-34, 52, 56, 63-67 are rejected under 35 USC §101 because the claimed invention is not supported by a well established utility.

The claims are drawn to a method for "prophylaxis" of migraine headaches. This term implies that headaches can be prevented. The term implies a 100% success rate. Suppose that, for example, one of the claimed compounds were administered to each of 1000 persons who had, in the past, shown a pronounced propensity for migraine headaches. If as a result of the administration, 999 of the patients never again developed a headache of any kind, and such a result would be wildly successful by any standard. But such a result would actually provide evidence that prevention had not been achieved. Applicants' data falls far short of the "bar" that would have to be overcome in demonstrating prevention or prophylaxis. It is suggested that the term at issue ("prophylaxis") be deleted.

Claims 20-28, 32-34, 52, 56, 63-67 are also rejected under 35 USC §112 first paragraph. Specifically, since the claimed invention is not supported by a well-established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

✧

The following is a quotation of 35 USC. §103 which forms the basis for all obviousness rejections set forth in the Office action:

> A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.
>
> Subject matter developed by another person, which qualifies as prior art only under subsection (f) and (g) of section 102 of this title, shall not preclude patentability under this section where the subject matter and the claimed invention were, at the time the invention was made, owned by the same person or subject to an obligation of assignment to the same person.
>
> This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103, the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made, absent any evidence to the contrary. Applicant is advised of the obligation under 37 C.F.R. 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103.

Claims 20-23, 25 are rejected under 35 U.S.C. §103 as being unpatentable over Szelke (USP 6,096,712).

Szelke discloses compound #331 (col 37) and compound #332 (col 38). ["Nag" represents noragmatine... see col 40, line 66]. Also disclosed (col 4, line 47) is that the compounds can be used to treat migraines.

The claims are rendered obvious for the case of "R" representing hydrogen that is substituted with EWG/EDG, or for the case of "R" representing alkyl that is substituted with EWG/EDG.

✦

Claims 20-23 are rejected under 35 U.S.C. §103 as being unpatentable over Kozhemyakin (USP 6,368,788).

Kozhemyakin discloses (col 37, line 67) the N-acetylated dipeptide Ac-Glu-Trp, and further discloses (col 25, line 52) that it can be used to treat migraine headaches. The disclosed peptide falls within the scope of claim 1 when the substituent variables are as follows:

R^1 = methyl;
R^2 = hydrogen;
R^3 = ethyl that is substituted with an electron withdrawing group (specifically, carboxyl);
n = 1;
R = methyl that is substituted once with carboxyl and once with indolylmethyl

Kozhemyakin does not disclose that carboxyl is electron withdrawing, and does not disclose that indolylmethyl is electronically different from hydrogen. However, both of these facts are well known to physical organic chemists.

Thus, the claims are rendered obvious.

✦

Claims 20-23 are rejected under 35 U.S.C. §103 as being unpatentable over Brennan (USP 6,716,810).

Brennnan discloses N-acetylated peptides that are cyclic or acyclic. See, for example, the following locations: col 10, line 20, col 24, line 39, and col 27, line

35+ . Also disclosed (col 55, line 25) is that the compounds can be used to treat migraines.

The claims are rendered obvious for the case of "R" representing hydrogen that is substituted with EWG/EDG, or for the case of "R" representing alkyl that is substituted with EWG/EDG.

✧

Claim 20 is rejected under 35 U.S.C. §103 as being unpatentable over Clozel (USP 5,696,116).

Clozel discloses a compound at col 6, lines 11-12, the name of which begins with the following: acetyl (3, 3-diphenyl-D-alanine)...

Clozel also implies (col 2, line 3) that the compound can be used to treat migraine headaches.

The claim is rendered obvious for the case of "R" representing hydrogen that is substituted with EWG/EDG, or for the case of "R" representing alkyl that is substituted with EWG/EDG.

✧

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Lukton whose telephone number is 571-272-0952. The examiner can normally be reached Monday-Friday from 9:30 to 6:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jon Weber, can be reached at 571-272-0925. The fax number for the organization where this application or proceeding is assigned is 571-273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 571-272-1600.

DAVID LUKTON
PATENT EXAMINER
GROUP 1800